

REMARKS

The January 11, 2011 Official Action and the references cited therein have been carefully reviewed. In view of the following remarks, favorable reconsideration and allowance of this application are respectfully requested.

At the outset, a shortened statutory response period of three (3) months was set forth in the January 11, 2011 Official Action. Therefore, the initial due date for response is April 11, 2011.

As another preliminary matter, the Examiner has indicated that claims 38-40, 43-47, 55, and 56 are allowed.

The Examiner has rejected claims 57-65 under 35 U.S.C. §103(a) as allegedly unpatentable over U.S Patent Application Publication No. 2001/0001040 in view of U.S Patent 5,902,610.

Lastly, claim 66 has been objected to as being dependent on a rejected base claim. The Examiner states that claim 66 would be allowable if rewritten in independent form to include all of the features of the base claim and any intervening claim(s).

The foregoing objection and rejection constitute all of the grounds set forth in the January 11, 2011 Official Action for refusing the present application.

In accordance with the instant amendment, claim 57 has been amended. Support for the amendment can be found throughout the application including, for example, previous claims 58 and 65. No new matter has been introduced into this application by reason of any of the amendments presented herewith.

In view of the reasons set forth in this response, Applicants respectfully submit that the 35 U.S.C. §103(a) rejection of claims 57-65 and the objection of claim 66, as set forth in the January 11, 2011 Official Action, cannot be maintained. These grounds of objection and rejection are, therefore, respectfully traversed.

**THE CLAIMS ARE NOT RENDERED OBVIOUS BY THE '040 APPLICATION IN
VIEW OF THE '610 PATENT**

The Examiner has rejected claims 57-65 under 35 U.S.C. §103(a) as allegedly unpatentable over the '040 application in view of the '610 patent. The '040 application allegedly discloses that IDO inhibitors including 1-MT are useful in the treatment of cancer. The '610 patent allegedly teaches that cisplatin is an anticancer agent that is effectively used against a broad spectrum of cancers. It is the Examiner's position that it would have been obvious to a skilled artisan to combine the above disclosures to arrive at the instantly claimed invention.

Applicants continue to respectfully disagree with the Examiner's position for the reasons of record. However, in the interest of expediting prosecution of the instant application, Applicants have amended claim 57 to recite that the cancer is breast cancer and that the chemotherapeutic agent is selected from the group consisting of paclitaxel, cisplatin, cyclophosphamide, and doxorubicin. Applicants note that the Examiner has indicated that claim 66 contains allowable subject matter. However, the Examiner has objected to claim 66 for depending from a rejected base claim. Notably, claim 66 recites the method of claim 57 wherein the cancer is breast cancer and the chemotherapeutic agent is cisplatin. Indeed, at page 4 of the instant Official Action, the Examiner states that "Applicant has provided evidence of an unexpected synergistic anti-cancer activity of the instantly claimed method (i.e. the combination therapy of 1MT and cisplatin) in the treatment of ... breast cancer." However, Applicants respectfully submit that evidence of unexpected synergistic anti-cancer activity has also been clearly provided for paclitaxel, cyclophosphamide, and doxorubicin. For example, Figures 5 and 11 of the instant application demonstrate unexpected synergy with these three chemotherapeutic agents (paclitaxel, cyclophosphamide, and doxorubicin) and 1MT against breast cancer. Hou et al.

(Cancer Res. (2007) 67:792-801; previously provided) also provide evidence that the co-administration of 1MT with the chemotherapeutic agent cyclophosphamide or paclitaxel led to unexpectedly synergistic treatment of breast cancer (see Figures 2A and 2B and July 7, 2008 Official Action response). Muller et al. (Nature Medicine (2005) 11:312-319) also provide further evidence of the unexpected synergy with the co-administration of 1MT and paclitaxel against breast cancer (see Figure 4 and July 7, 2008 Official Action response).

In view of all of the foregoing, Applicants respectfully submit that the rejection of claims 38, 39, 41-47, and 53-56 under 35 U.S.C. §103(a) is untenable and request its withdrawal.

STATEMENT OF SUBSTANCE OF INTERVIEW

This Statement of Substance of Interview is being submitted in accordance with §713.04 of the Manual of Patent Examining Procedure to make of record a telephone interview held between Examiners Christopher Stone and the undersigned on or about March 28, 2011.

A telephonic interview was held on or about March 28, 2011 between the undersigned and Examiner Stone for the purpose of discussing the prior art rejection set forth in the January 11, 2011 Official Action and potential claim amendments to claim 57. More specifically, the undersigned argued that unexpected synergistic anti-cancer activity was observed with chemotherapeutic agents other than cisplatin against breast cancer. Examiner Stone indicated he would consider an amendment to the claims reciting those chemotherapeutic agents which have shown unexpected synergistic anti-cancer activity. No agreement with regard to the claims was reached.

This Statement of Substance of Interview is being filed with the reply to the last Official Action in accordance §713.04 of the MPEP.

CONCLUSION

It is respectfully requested that the amendments presented herewith be entered in this application, since the amendments are primarily formal, rather than substantive in nature. The instant amendment is believed to clearly place the pending claims in condition for allowance. In any event, the claims as presently amended are believed to eliminate certain issues and better define other issues which would be raised on appeal, should an appeal be necessary in this case.

In view of the foregoing remarks, it is respectfully urged that the objection and rejection set forth in the January 11, 2011 Official Action be withdrawn and that this application be passed to issue.

In the event the Examiner is not persuaded as to the allowability of any claim, and it appears that any outstanding issues may be resolved through a telephone interview, the Examiner is requested to call the undersigned at the phone number given below.

If a fee is required or an overpayment is made, the Commissioner is authorized to charge or credit the deposit account of the undersigned, Account No. 04-1406.

Respectfully submitted,
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